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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------|------------------|
| 09/903,374 | 07/11/2001 | Steve A. Herweck | ATA-297 | 8317 |
| 959 | 7590 | 10/03/2003 | EXAMINER | |
| LAHIVE & COCKFIELD 28 STATE STREET BOSTON, MA 02109 | | | MATHEW, FENN C | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3764 | |
| | | | DATE MAILED: 10/03/2003 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/903,374 | | HERWECK ET AL. | |
| | Examiner | | Art Unit | |
| | Fenn C Mathew | | 3764 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-9 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-9 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 28, 2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 6-7, and 11-¹²~~15~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu (U.S. 5,061,276) in view of Von Albertini (U.S. 4,670,008). Referring to claim 1, Tu discloses a prosthesis comprising a first tube of polymeric material, a membrane of polymer material positioned about the exterior surface of the first tube, and a support structure wound along a winding axis about an exterior surface of the membrane (col. 5, lines 25-45), to form axially spaced ridges that enable the material to substantially close a hole that is created when the material is punctured, the

membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding (col. 7, lines 5-20). Tu is silent with regards to the relationship between the outer diameter of a needle and the space between ridges but does teach that it is preferable to have the diameter of the support structure range from 20-50 microns (col. 11, lines 17-19), and have the support structure wound at the rate of 4-10 per centimeter (col. 18, lines 55-57). Von Albertini teaches needles used for injection, and specifically states that it is well known in the art to have a needle diameter of 1.6-2.2 mm. Therefore it would have been obvious to the skilled artisan to use a needle with a diameter in the above mentioned range, and furthermore, a support structure with a diameter of 50 microns and wound at the rate of 4 per centimeter would have a space between the ridges that was approximately 1.225 times a 1.6 mm diameter needle.

4. Referring to claim 6, Tu discloses the nodes being perpendicular to the direction of expansion. Inherently the nodes are oriented at an angle other than 0 degrees with respect to the wound support structure (col. 8, lines 20-26).

5. Referring to claim 7, Tu discloses the claimed invention except for the specific angle of the nodes with respect to the winding axis. The feature of having the nodes at a 90-degree angle with respect to the winding axis would be a matter of obvious design choice within the realm of one with ordinary skill in the art, as applicant has not provided evidence that the stated angle provides any advantage, nor that any unexpected result would arise from the configuration disclosed by Tu.

6. Referring to claim 12, Tu discloses a method of making a prosthesis comprising the steps of providing a first tube of biologically compatible material, positioning a

membrane of polymer material about the exterior surface of the first tube, and winding at least one support structure along a winding axis about the membrane, capable of enabling the material to substantially close a hole, the membrane having a microstructure of nodes interconnected by fibrils effective to facilitate bonding of the support structure to the membrane and inhibit delamination (col. 15, lines 20-30) of the support structure from the membrane. Tu is silent with regards to the relationship between the outer diameter of a needle and the space between ridges but does teach that it is preferable to have the diameter of the support structure range from 20-50 microns (col. 11, lines 17-19), and have the support structure wound at the rate of 4-10 per centimeter (col. 18, lines 55-57). Von Albertini teaches needles used for injection, and specifically states that it is well known in the art to have a needle diameter of 1.6-2.2 mm. Therefore it would have been obvious to the skilled artisan to use a needle with a diameter in the above mentioned range, and furthermore, a support structure with a diameter of 50 microns and wound at the rate of 4 per centimeter would have a space between the ridges that was approximately 1.225 times a 1.6 mm diameter needle.

7. Claims 2-3, 5, and 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu in view of Von Albertini as applied to claim 1 above, and further in view of Martakos (U.S. 5,897,587). Referring to claim 2, Tu discloses the claimed invention except for the specific material of the support structure. The feature of having the support structure made of metal wire is a design consideration within the level of one with ordinary skill in the art as evidence by Martakos, who teaches an analogous device wherein the support structure comprises a metal wire. (Column 6, lines 34-35).

8. Referring to claim 3, Tu discloses the claimed invention except for a support covering. Martakos discloses an analogous device having a support covering (30). It would have been obvious to one having ordinary skill in the art at the time of invention to provide the invention of Tu with a support covering as taught by Martakos in order to provide a protective covering.

9. Referring to claims 8-9, Tu discloses the claimed invention including a membrane formed from a polymer material having a microstructure of nodes interconnected by fibrils with a porosity that is less than that of the first tube. Tu is silent with regards to the size of the nodes of the membrane compared to the first tube. Martakos discloses an analogous device and discloses the nodes of the membrane being smaller than the nodes of the first tube, and specifically that the nodes of the membrane are at least 10% smaller than the nodes forming the first tube (col. 3, lines 4-10). It would have been obvious to one having ordinary skill in the art at the time of invention to have the nodes of the membrane be smaller than the nodes of the first tube in order to provide a lower porosity for the membrane.

10. Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tu in view of Von Albertini as applied to claim 1 above, and further in view of Kalis (U.S. 5,609,624). Referring to claims 13-15, Tu as modified above discloses the claimed invention except for the manner in which the membrane with nodes and fibrils are positioned on the axis. Kalis discloses in col. 3, lines 5-20 that it is desirable to have a membrane with the nodes and fibrils helically or spirally wound around the axis of the graft in order to provide superior tensile strength. Therefore, it would have been

obvious to one having ordinary skill in the art at the time of invention to have the membrane of Tu spirally or helically wound around the longitudinal axis of the graft in order to provide superior tensile strength.

Response to Arguments

11. Applicant's arguments with respect to claims 1 and 12 have been considered but are moot in view of the new ground(s) of rejection. As pointed out above, using a fiber diameter of 50 microns wrapped at the rate of 4 turns per centimeter, one can figure out that the distance between ridges is approximately 1.96 mm, which correlates to a ratio of 1.225 times a 1.6 mm diameter needle. With regards to claim 7, applicant has established the criticality of an angle greater than 0 degrees (as evidenced on page 7, line 26 – page 8 line 7). As mentioned above, Tu inherently discloses the nodes at an angle greater than 0 degrees with respect to the winding axis, which can have an angle of 30-80 degrees.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fenn C Mathew whose telephone number is (703) 305-2846. The examiner can normally be reached on Monday - Friday 9:00am - 5:30pm.

The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Art Unit: 3764

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.



NICHOLAS D. LUCCHESI
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gem
fcm

September 23, 2003